

PLEASE AMEND THIS APPLICATION AS FOLLOWS:

In The Title:

Change the title of the invention to:

-- NOVEL VIRAL VECTOR AND PACKAGING CELL LINE --

In The Claims:

Amend claims 68 and 81-84 as follows:

68. (Amended) A first vector selected from the group consisting of (i) a viral vector comprising a viral nucleic acid and a viral vector packaging component or components, (ii) a viral nucleic acid, and (iii) a nucleic acid construct,

wherein when introduced into a packaging cell said first vector is [capable of producing] produces a second vector selected from the group consisting of (a) a second viral vector, (b) a viral nucleic acid, and (c) a second nucleic acid construct, each [being capable of] expressing an exogenous gene or exogenous nucleic acid sequence when present in a target cell of interest,

C1 wherein said first vector [is capable of producing in said packaging cell said second vector] produces said second vector when present in said packaging cell, and

wherein said packaging cell [is capable of providing] provides one or more packaging components for said second viral nucleic acid,

wherein said second viral nucleic acid or said second nucleic acid construct is structurally different from said first (i) viral nucleic acid or said first (ii) nucleic acid construct, or more than one packaging component for said second viral vector is different from said first viral vector packaging component or components (b), or both.

81. (Amended) The packaging cell line of claim 77, wherein any nucleic acid sequences coding for both the surface or envelope components are stably integrated in a chromosome or chromosomes of said packaging cell line.

82. (Amended) The packaging cell line of claim 77, wherein a nucleic acid sequence [of] coding for a surface or envelope component is stably integrated in a chromosome or chromosomes of said packaging, and a sequence of another surface or envelope component is transiently expressed.

83. (Amended) The packaging cell line of claim 77, wherein a nucleic acid sequence [of] coding for said envelope component is stably integrated in a chromosome or chromosomes of said packaging cell line, and a nucleic acid sequence [of] coding for said surface component is transiently expressed.

84. (Amended) The packaging cell line of claim 77, wherein any nucleic acid sequences coding for both the surface or envelope components are transiently expressed.

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disclosure. Entry of the above amendments and new claims is respectfully urged.

Sequence Listing Statement

Applicants and their attorney acknowledge the Examiner's comments regarding their sequence listing for this application. In response, Applicants wish to state that the sequence listing in their application is the same as that in the parent application, U.S. Patent Application Serial No. 08/822,963, filed on March 21, 1997. Furthermore, a paper copy of the sequence listing is being submitted herewith attached as Appendix A. The attached paper copy (Appendix A) is identical to the computer readable form (CRF) of the sequence listing submitted in the aforementioned parent application (Serial No. 08/822,963). It is respectfully requested that the CRF in the parent application be used to prepare a file for this offspring application.

Submission of Information Disclosure Statement

Applicants' attorney and his paralegal are presently retrieving articles that may be material to the examination of this application. As soon as the retrieval has been completed, the articles will be submitted to the Patent and Trademark Office and the Examiner in the form of an Information Disclosure Statement.

Formal Drawings

Applicants acknowledge the Notice of Draftperson's Patent Drawing Review dated May 7, 1998 that was issued with the June 12, 1998 Office Action. As soon as an indication of allowability is obtained for any of their claims, Applicants will submit new formal drawings taking into consideration the items marked in the May 7th patent drawing review.

The First Rejection Under 35 U.S.C. §102

Claim 68-79 and 81-84 stands rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Wong-Staal et al., U.S. Patent No. 5,650,309, issued on July 22, 1997 on an application filed on May 16, 1995. In the Office Action (pages 2-3), the Examiner stated:

Applicants claim a viral vector (i.e. a vector derived from a retrovirus or adeno-associated virus (AAV)) wherein said vector can produce a second vector or nucleic acid when introduced into a packaging cell and wherein the vector is capable of expressing a heterologous sequence in a target cell of interest.

Wong-Staal et al. (U.S. Patent #5,650,309, issued 7/22/97, priority back to 5/16/95, see whole document, particularly Figs. 11-13, Claims 1-15 and Columns 6-7 and 16-18) recites the generation of viral vectors comprising sequences from retrovirus and AAV genomes wherein said vectors can produce a second vector (i.e. single or double stranded RNA or DNA), wherein said vectors comprise a promoter(s), integration sequence, terminator sequence, etc. and packaging cells for these vectors wherein the packaging cell comprises sequences for the envelope portion of the vector (optionally stably integrated into the chromosomal DNA of the cell) and two packaging components for the surface or envelope of the vector (i.e. packaging components for the AAV or retroviral vectors can be provided in the packaging cell). Wong-Staal et al. therefore teaches the claimed invention.

The anticipation rejection is respectfully traversed.

It is believed that the Wong-Staal's patent does not anticipate the instant invention because the former does not disclose Applicants' instantly claimed elements wherein the second viral nucleic acid or the second nucleic acid construct is structurally different from the first (i) viral nucleic acid or the first (ii) nucleic acid construct, or more than one packaging component for the second viral vector is different from said first viral vector packaging component or components (b), or both.

In light of the lack of identity between Applicants' instantly claimed invention and Wong-Staal's cited patent, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

The Second Rejection Under 35 U.S.C. §102

Claims 68 and 70-74 stand rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al. ["Targeting of Retroviral Vectors for Gene Therapy," Human Gene Therapy 4:129-141 (1993)]. In the Office Action (page 4), the Examiner stated:

Applicants claim a first vector which can be a viral nucleic acid wherein said first vector is capable of producing a second vector (of a different chemical nature) in a packaging cell wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter(s), terminator sequences, enhancers, etc.

Salmons et al. (Human Gene Therapy, Vol. 4, 1993, pp. 129-141, see whole article, particularly Fig. 3 and pages 133-135) recites a first retroviral vector wherein said vector is capable of producing a second vector (of a different chemical nature) in a packaging cell line wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter, enhancer, terminator sequences, etc. Therefore, Salmons et al. teaches the claimed invention.

The anticipation rejection is respectfully traversed.

It is believed that Salmons' review article does not anticipate the instant invention because no identity of material elements exists with Applicants' claimed elements. More specifically, Salmons et al. fail to disclose Applicants' instantly claimed elements wherein the second viral nucleic acid or the second nucleic acid construct is structurally different from the first (i) viral nucleic acid or the first (ii) nucleic acid construct, or more than one packaging component for the second viral vector is different from said first viral vector packaging component or components (b), or both.

In light of the lack of identity between Applicants' instantly claimed invention and Salmons' cited review article, reconsideration and withdrawal of the rejection under 35 U.S.C. §102 is respectfully requested.

§112 is respectfully requested.

Having overcome both grounds of rejection, an early indication as to the allowability of the present invention is respectfully sought.

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